



Steven K. Young, Director

FDA, STERIS Corporation Detail Fire Risk with Amsco Sonic Energy Cleaner

DES MOINES, IOWA (September 5, 2006) – The Iowa Department of Inspections and Appeals (DIA) was recently notified by the federal Centers for Medicare & Medicaid Services (CMS) of a potential fire risk associated with the use of Amsco Sonic Energy Cleaner and/or an Amsco Sonic Energy Console. The equipment, manufactured by the STERIS Corporation of Mentor, Ohio, between November 2000 and January 2005, is used for cleaning reusable medical equipment. The affected products bear serial numbers 0432000018 to 0403105051. The serial number is located on the product identification plate, located on the base of the unit, beneath the front door.

According to the U.S. Food and Drug Administration (FDA), which issued the fire risk warning, the location of the lid switch cable wiring harness in the affected products makes them susceptible to water damage to the electrical connections. If this occurs, it can cause overheating of the electrical system in the unit and lead to damage of the wiring harness resulting in smoking, sparking, and fire.

Healthcare professionals are instructed to follow proper safety precautions such as allowing the instrument tray to drain fully before moving to the next cleaning station to prevent water from contacting the electrical wiring while using this device. In the event of overheating in the electrical system and damage of the wiring harness, the immediate effect is that the unit becomes unusable and must be repaired. In the event of an incident, there is a potential risk of staff personnel in cleaning area sustaining smoke inhalation.

The electrical system is self-enclosed within stainless steel on all sides with a galvanized steel back plate. The risk of injury to resident patients is low if a Sonic Cleaner or Sonic Console is not located in patient care areas. The manufacturer has initiated a field correction and a STERIS technician will visit account holders to replace the wire harness and associated components of the affected units.

For further information or if you have questions regarding the servicing of your unit, please contact STERIS Field Service Dispatch at 1-800-288-2805. Units made after January 2005 have the wiring harness routed in a manner which alleviates water damage and have electrical connections that are water resistant and are not included in this field correction.

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STERIS equipment

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<http://www.state.ia.us/government/dia/page20.html>.